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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,587	07/10/2002	Leszek Wojnowski	VOS-30	7615
1473	7590	11/25/2008		
ROPER & GRAY LLP PATENT DOCKETING 39/361 1211 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8704			EXAMINER FETTEROLF, BRANDON J	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 11/25/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/070,587

**Applicant(s)**

WOJNOWSKI ET AL.

**Examiner**

BRANDON J. FETTEROLF

**Art Unit**

1642

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-8, 12, 13, 37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) 1C and 41(a)-(e) and (k)-(p) is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 and 41 (f)-(j) is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 12, 13, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to the Notice of Non-Responsiveness***

Applicants response to the Notice of Non-Responsiveness filed on 7/31/2008 is acknowledged. In the instant case, the Examiner acknowledges Applicants assertions that the April 22, 2008 reply noted that "SEQ ID NO: 155 is encoded by SEQ ID NO: 154 (see e.g., original claim 1 (a), which comprises SEQ ID NO: 90). However, it is unclear how one is suppose to come to this conclusion, e.g., which comprises SEQ ID NO: 90, in view of original claim 1 reciting over 50 nucleic acid sequences, wherein SEQ ID NO: 90 and SEQ ID NO: 154 are both recited, but no nexus is taught. Nonetheless, after the conversation with Applicants representative, the Examiner agrees with Applicants assertions that the previous response was fully responsive.

### ***Response to Amendment***

The Amendment filed on 4/22/2008 in response to the previous Non-Final Office Action (10/22/2007) is acknowledged and has been entered.

Claims 1, 4-8, 12-13, 37, 39-41 are currently pending.

Claims 1C and 41(a)-(e) and (k)-(p) are withdrawn from consideration as being drawn to non-elected inventions. (see below for an explanation)

Claims 1 (a)-(b) and (d), 4-8, 12-13, 37, 39-41 (f)-(j) are under consideration.

Note: The nucleic acid sequence of SEQ ID NO: 90 was elected in the election to the Restriction Requirement of 4/25/2005, which correspond to nucleic acid residues 166 to 176 of SEQ ID NO: 154. As such, a polynucleotide comprising a nucleic acid sequence of positions 157 to 171 of SEQ ID NO: 154, for example, does not read on the elected SEQ ID NO.. Similarly, a polynucleotide sequence comprising 15 nucleotides of SEQ ID NO: 154, wherein the 15 nucleotides of SEQ ID NO: 154, wherein the 15 nucleotides comprise a sequence that comprises a T at the position that corresponds to position 6 of SEQ ID NO: 90 does not appear to read on the elected SEQ ID NO: since Applicants assert that the polynucleotide of 1 (c) is directed to a polynucleotide that comprises a sequence that need

not comprise exactly SEQ ID NO: 90, but can comprise a sequence that has one or more differences from SEQ ID NO: 90 such as a deletion, addition or other substitution (see page 4, Applicants 8/27/2008 Remarks).

**Rejections Maintained:**

Claims 1, 4-8, 12-13 and 39-40 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant case, claim 1 recites "[A]n isolated polynucleotide encoding a variant human cytochrome P450 3A4 monooxygenase polypeptide or fragment thereof wherein the polynucleotide is selected from the group consisting of: 1.

(d) a polynucleotide encoding a CYP3A4 polypeptide, wherein said polypeptide comprises a sequence corresponding to SEQ ID NO: 155, and comprises an amino acid substitution of T to M at the position that corresponds to position 21 of SEQ ID NO: 155, ...." However, it is unclear what Applicants are claiming as his or her invention for polynucleotides (c) and/or (e). For example, the polynucleotide of SEQ ID NO: 90 already appears to comprise a T at the position that corresponds to position 6 of SEQ ID NO: 90. Similarly, the polypeptide of corresponding to SEQ ID NO: 155 already appears to comprise the amino acid M at the position corresponding to position 21 of SEQ ID NO: 155. As such, polynucleotides (c) and (e) will be interpreted for prior art purposes as being a polynucleotide sequence comprising SEQ ID NO: 90 and a polynucleotide sequence encoding a polynucleotide comprising the sequence of SEQ ID NO: 155.

In response to this rejection, Applicants assert that similar to (c) of claim 1, the specification makes clear that a "corresponding position" as used in the claims means that the location of the position takes into consideration the flanking nucleotides/amino acids and that a "corresponding position might have a different position number compared to a reference sequence due to deletions or additions elsewhere in the polynucleotide or might be flanked by sequences containing substitutions. Such a "corresponding position" is still identifiable by the flanking nucleotides/amino acids.

These arguments have been carefully considered, but are not found persuasive.

In the instant case, the Examiner recognizes that Applicants analysis of claim 1 (c) while correct does not appear to apply to claim 1(d). In particular, the Examiner recognizes that the polynucleotide of Claim 1(d) encodes a polynucleotide comprising the sequence corresponding to SEQ ID NO: 155. As such, the polypeptide encoded by the claimed polynucleotide comprise SEQ ID NO: 155. In contrast, the polynucleotide of amended claim 1(c) does not appear to comprise the sequence corresponding to SEQ ID NO: 90 anymore.

Claims 37 and 41 (f)-(j) appear to be free of the prior art and are in condition for allowance.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf  
Primary Examiner  
Art Unit 1642

/Brandon J Fetterolf/  
Primary Examiner, Art Unit 1642